DEC 2 9 2011



GE Healthcare 510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: December 14, 2011

Submitter: GE Healthcare

9900 W. Innovation Dr. Wauwatosa, WI 53226

Primary Contact Person: Bryan Behn

Regulatory Affairs Manager

GE Healthcare T:(414)721-4214 F:(414)918-8275

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Yalan Wu

Regulatory Affairs Manager

GE Healthcare

T: +86 510 8527 8652 F: +86 510 8527 7347

<u>Device:</u> <u>Trade Name:</u> LOGIQ i, LOGIQ e, Vivid e <u>Common/Usual Name:</u> LOGIQ i, LOGIQ e, Vivid e

Classification Names: Class II

Product Code: Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-

IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570,

90-ITX

Predicate Device(s): LOGIQ i, LOGIQ e, Vivid e, K102256

LOGIQ E9 K110943

Device Description:

The LOGIQ i/e & Vivid e is a full-featured, compact and extremely portable ultrasound system consisting of a main console chassis with integrated keyboard, a color video LCD type display and several interchangeable electronic-array transducers. It has digital acquisition, processing and display capability and operates from an integrated battery or a separate power supply/charger. It is used primarily where portability, size and convenience are essential and is available in three variations: LOGIQ e is for general purpose radiology imaging having a variety of options to tailor it for use by the medical specialist for use in various departments and patient care areas (e.g., OR,



GE Healthcare

510(k) Premarket Notification Submission

ER & outpatient care). Accordingly it has various configurations (Software option/standard and probes supporting) for different packages (Nerve, ED, and GI). LOGIQ i is a full-featured premium radiology system suitable for physician rounds in a hospital, nursing home where a broader range of high performance is needed.

Vivid e is similar to the LOGIQ e with an emphasis on cardiology examinations.

Intended Use:

The LOGIQ i/e & Vivid e is a general purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Intra-operative (abdominal, thoracic and PV), Musculo-skeletal Conventional & Superficial, Transesophageal, Transrectal and Transvaginal, and Thoracic/Pleural for motion/sliding and fluid detection.

Technology:

The LOGIQ i/e & Vivid e employs the same fundamental scientific technology as its predicate.

<u>Determination of</u> Substantial Equivalence:

<u>Determination of Summary of Non-Clinical Tests:</u>

The LOGIQ i/e & Vivid e and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification
- Simulated use testing (Validation)

Transducer material and other patient contact materials such as needle guidance kits are biocompatible.



GE Healthcare

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Summary of Clinical Tests:

The subject of this premarket submission, LOGIQ i/e & Vivid e, did not require clinical studies to support substantial equivalence.

Conclusion:

GE Healthcare considers the LOGIQ i/e & Vivid e to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).



Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Mr. Bryan Behn GE Healthcare Regulatory Affairs Manager 9900 W Innovation Drive WAUWATOSA WI 53226

JAN 19 2012

Re: K113690

Trade/Device Name: GE LOGIQ I, LOGIQ e and Vivid e Diagnostic Ultrasound

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: December 14, 2011 Received: December 15, 2011

Dear Mr. Behn:

This letter corrects our substantially equivalent letter of December 29, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE LOGIQ I, LOGIQ e and Vivid e Diagnostic Ultrasound, as described in your premarket notification:

Transducer Model Number

4C-RS	<u>12L-RS</u>	<u>6S-RS</u>
8C-RS	16L-RS	<u>P2D</u>
E8C-RS	i12L-RS	6Tc-RS
8L-RS	i/t739-RS	<u>L8-18i-RS</u>
9L-RS	3S-RS	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Michael O'Hara at (301) 796-0294.

Sincerely Yours,

Mary S. Pastel, Sc.D.

Director

Division of Radiological Devices Office of In Vitro Diagnostic Device

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Evaluation and Safety

Center for Devices and Radiological Health

Enclosure(s)



- GE Healthcare 510(k) Premarket Notification Submission

510(k) Number (if known):

Device Name:

GE LOGIQ I, LOGIQ e and Vivid e Diagnostic Ultrasound

Indications for Use:

The LOGIQ i/e & Vivid e is a general purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Intraoperative (abdominal, thoracic and PV), Musculo-skeletal Conventional & Superficial, Transesophageal, Transrectal and Transvaginal, and Thoracic/Pleural for motion/sliding and fluid detection.

Prescription Use_x_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use_N/A_ (Part 21 CFR 801 Subpart C)
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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) Number_

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GE Healthcare 510(k) Premarket Notification Submission



Indications For Use Forms

The following Indication for Use forms are attached.

System: GE LOGIQ i/e & Vivid e

Transducer: 4C-RS

Transducer: 8C-RS

Transducer: E8C-RS

Transducer: 8L-RS

Transducer: 9L-RS

Transducer: 12L-RS

Transducer: 16L-RS

Transducer: i12L-RS

Transducer: i/t739-RS

Transducer: 3S-RS

Transducer: 6S-RS

Transducer: P2D

Transducer: 6Tc-RS

Transducer: L8-18i-RS

The following forms represent indications with clinical applications and exam types along with the modes of operation for the LOGIQ i/e & Vivid e system and for all of its probe/mode combinations. Combinations identified by "N" are new while "P" represents those previously cleared with the unmodified LOGIQ i/e & Vivid e. The subject modification does not alter the previously cleared system level indications or clinical applications.

Division of Regliological Devices

Times of in Vitro Diagnostic Device Evaluation and Safety

510K_5 113 690

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GE Compact Ultrasound System LOGIO i, LOGIO e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

						de of Op					
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppled	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P	
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P_	P	P	P	P	P	P	P	P	P	
Small Organ [2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic	P	P	P	P	P	P	P	Р	P	P	├
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	├
Cardiac ^[3]	P_	P	P	P	P	P	P	P	P	P	
Peripheral Vascular	P	P	P	P	P	<u> </u>	P	P	P	P	├
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P	L
Thoracic/Pleural(specify)[4]	P	P	P	P	P	P	P	P	P	P	_
Other ^[5]	P	P	P	P	P	P	P	P	P	P	_
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P	P	
Transrectal	P	P	P		P		P	P	P	↓	_
Transvaginal	P	P	P		P	1	P	P	P	↓	1_
Transurethral		_						ļ	-	1	1
Intraoperative(specify)[6]	P	P	P		P		P	P	P	P	1_
Intraoperative Neurological										· .	\perp
Intravascular										↓	\perp
Laparoscopic											

Laparo	scopic						L					
N = nev	indication; P = prev	iously	cleared	by FDA;	E = adde	d under A	ppendix	E			_	
Notes:	[1] Abdominal inclu	ides GY	N and	Urologica	t		•	\sim	7/	< F	211	1
	[2] Small organ incl	ludes br	east, tes	stes, thyro	id.		-		Jan		<u>wy</u>	
	[3] Cardiac is Adult	and Pe	diatric.					Di		sion Sign-Off Radiological		
	[4] For detection of	fluid ar	id pleur	al motion	/sliding;		Office	valuation a	and Safety			
	[5] Other use include	les Urol	ogy/Pro	state					K 11	2/0	(A)	
	[6] Intraoperative in						-	10K	$D\Pi$	204	W.	
	[*] Combined mode	s are B	/M, B/P	WD, B/C	olor/PW	D, B/Powe	r/PWD.					
	[*] Coded Pulse is f	or digita	ally enc	oded harm	ronics.							

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with 4C-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

.						Mode of				0 1 1	Out
Clinical Application Anatomy/Region of Interest	В	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P		P		P	P	P	P	
Abdominal ^[1]	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ [2]											
Neonatal Cephalic											ļ
Adult Cephalic											
Cardiac ^[3]											—
Peripheral Vascular								ļ			Ь—
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural(specify)[4]	P	P	P		P		P	P	P	P	
Other ^[5]	P	P	P		P		P	P	P	P	$oxed{oldsymbol{ol}}}}}}}}}}}}}}}}}}$
Exam Type, Means of Access											<u> </u>
Transesophageal											
Transrectal											
Transvaginal								<u> </u>			1
Transurethral											
Intraoperative (specify)[6]											
Intraoperative Neurological											
Intravascular											
Laparoscopic					ddad ynd						

Intravascular								——————————————————————————————————————
Laparoscopic						l	ļ ,	
N = new indication; P = prev Notes: [1] Abdominal inclu [2] Small organ incl [3] Cardiac is Adult [4] For detection of [5] Other use includ [6] Intraoperative in [*] Combined mode [*] Coded Pulse is for	des GYN and U udes breast, test and Pediatric. fluid and pleura es Urology/Pros cludes abdomin s are B/M, B/PV	rological es, thyroid. I motion/slid state al, thoracic a VD, B/Colon	ing; nd periphera /PWD, B/Po	Office of the fall	Division of In Vitro Diag		gical Device	
(DI EACE DO NOT	WOTTE DELO	V TIDE I DI	E CONTIN	TIE ON ANO	THED DAGE	IE NEED	ED)	

Prescription Use (Per 21 CFR 801.109)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with 8C-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

						ode of O					
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P		P		P	P	P		
Pediatric	P	P	P		P		P	P	P		
Small Organ [2]	P	P	P		P		P	P	P	<u> </u>	<u> </u>
Neonatal Cephalic	P	P	P		P		P	P	P		
Adult Cephalic									ļ		
Cardiac ^[3]	P	P	P		P		P	P	P		
Peripheral Vascular	P	P	P		P		P	P	P		
Musculo-skeletal Conventional	P	P	P		P		P	P	P		
Musculo-skeletal Superficial	Z	N	N		N		N	N	N		
Thoracic/Pleura(specify)[4]	P	P	P		P		P	P	P		<u></u>
Other[5]				}							<u></u>
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal							<u></u>				
Transurethral											
Intraoperative (specify)[6]											
Intraoperative Neurological											
Intravascular											
Laparoscopic				. E model			1				

Laparo	scopic									
N = nev	v indication; P = prev	iously cleared	by FDA; E	added und	er Appendix	E				
Notes:	[1] Abdominal inclu [2] Small organ incl [3] Cardiac is Adult [4] For detection of [5] Other use includ [6] Intraoperative in [*] Combined mode [*] Coded Pulse is for	udes breast, tes and Pediatric. fluid and pleur es Urology/Pro cludes abdomin s are B/M, B/P	tes, thyroid. al motion/slistate al, thoracic WD, B/Colo	and peripher/PWD, B/	ral;	of In Vitro Di	n of Radi	S /A Sign-Off) clogical De Device Eval	vices tuation and	l Safet

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with E8C-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					M	ode of Op					
Clinical Application Anatomy/ Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic		•									
Fetal / Obstetrics	P	P	P		P		P	P	P		
Abdominal ^[1]	P	P	P		P		P	P	P		
Pediatric											
Small Organ [2]			<u> </u>								
Neonatal Cephalic											_
Adult Cephalic											<u> </u>
Cardiac			<u> </u>							<u> </u>	
Peripheral Vascular				<u> </u>			ļ				
Musculo-skeletal Conventional											L.
Musculo-skeletal Superficial											
Thoracic/Pleura(specify) [4]											
Other[5]	P	P	P		P		P	P	P		
Exam Type, Means of Access											
Transesophageal								1			L_
Transrectal	P	P	P		P		P	P	P		
Transvaginal	P	P	P		P		P	P	P	<u> </u>	
Transurethral										<u> </u>	
Intraoperative (specify)[6]											
Intraoperative Neurological											
Intravascular											
Laparoscopic								1			

Lapan	scopic									
i = nev	v indication; P = previous	y cleared by FDA;	E = ado	led under	Appendix	E			2	
Votes:	[1] Abdominal includes	GYN and Urologic	al		•		n_{c}	54	14.0	
	[2] Small organ includes	breast, testes, thyr	oid.		•		Wine.	ision Sign-C		
	[3] Cardiac is Adult and	Pediatric.					Division of			
	[4] For detection of fluid	and pleural motion	n/sliding	;	Of	fice of In 1	Vitro Diagno	stic Device	Evaluation	n and Safety
	[5] Other use includes U	rology/Prostate					KII	2/0	10	
	[6] Intraoperative include	es abdominal, thor	cic and	peripheral	;	510K_	$\Gamma \Gamma \Gamma$		1V	
	[*] Combined modes are	B/M, B/PWD, B/O	Color/PW	D, B/Pov	ver/PWD.					

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109)

[*] Coded Pulse is for digitally encoded harmonics.

GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with 8L-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

L						Aode of O					
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ [2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic			<u> </u>					<u> </u>			
Adult Cephalie								L	ļ		
Cardiac ^[3]	P	P	P		P		P	P	P		
Peripheral Vascular	P	P	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P		
Musculo-skeletal Superficial											
Thoracic/Pleural(specify)[4]								<u> </u>		<u> </u>	<u> </u>
Other ^[5]							L		<u> </u>		
Exam Type, Means of Access											
Transesophageal								<u> </u>			
Transrectal											<u> </u>
Transvaginal									1	<u> </u>	<u> </u>
Transurethral											ļ
Intraoperative (specify) [6]	P	P	P		P		P	P	P	<u> </u>	<u> </u>
Intraoperative Neurological											
Intravascular											
Laparoscopic	1		1				1		1		

Laparo	scopic					L					<u> </u>	
V = nev	v indication; P = prev	iously	cleared	by FDA	E = adc	led under	Appendix	E			0	
Notes:	[1] Abdominal inch	ides G	YN and	l Urologi	cal			1	May.	.5/	0-X	0
	[2] Small organ incl	udes t	reast, te	estes, thy	roid.		•		(Div	ion Sign-C)ti)	
	[3] Cardiac is Adult	and P	ediatric				~		Division of F	Redictioning	Doudoon	
	[4] For detection of	fluid a	nd pleu	ral moti	on/sliding	;	Om	Ce of In V	itro Diagnos	tic Device	Evaluation	and Satety
	[5] Other use include	es Urc	logy/Pa	rostate				E40W	K11.0	691	γ	
	[6] Intraoperative in						ıl;	510K	11:0	<u> </u>		
	[*] Combined mode					/D, B/Po	wer/PWD	•				
	[*] Coded Pulse is for	or digi	tally en	coded ha	rmonics.							

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with 9L-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					M	ode of Op					
Clinical Application Anatomy/Region of Interest	В	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ [2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic						ļ					
Adult Cephalic				<u> </u>			ļ				
Cardiac ^[3]							<u> </u>			ļ	
Peripheral Vascular	P	P	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	
Musculo-skeletal Superficial	N	N	N		N		N	N	N	N	
Thoracic/Pleural(specify)[4]	N	N	N		N		N	N	N	N	
Other ^[5]											
Exam Type, Means of Access											
Transesophageal											
Transrectal							ļ				
Transvaginal								<u> </u>		1	
Transurethral								<u> </u>		↓	<u> </u>
Intraoperative (specify)[6]	P	Р	P		P		P	P	P	P	
Intraoperative Neurological										<u> </u>	
Intravascular											↓ _
Laparoscopic		1	1	1			1		<u> </u>		<u></u>

Laparo	scopic										
	midication; P = previous previous previous previous previous (1) Abdominal incluing [2] Small organ incluing [3] Cardiac is Adult [4] For detection of [5] Other use including [6] Intraoperative in [*] Combined model	udes GYN ludes bread and Pedia fluid and les Urolog noludes abo	and Urologi st, testes, thy stric. pleural moti y/Prostate dominal, tho	cal roid. on/sliding racic and	; peripheral	Office o	Divisor to Vitro	(Division sion of Radio	ological De	vices uation ar	nd Safety
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Prescription Use (Per 21 CFR 801.109)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with 12L-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

1					M	ode of Op					
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics			<u> </u>								_
Abdominal	N	N	N		N		N	N	N	N	
Pediatric	P	P	P		P		P	P	P	P	ļ
Small Organ [2]	P	P	P_		P		P	P	P	P	<u> </u>
Neonatal Cephalic											Ļ_
Adult Cephalic											<u> </u>
Cardiac							L				
Peripheral Vascular	P	P	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	L
Musculo-skeletal Superficial	P	P	P		P		P	Р	P	P	
Thoracic/Pleural(specify)[4]	P	P	P		P		P	P	P	P	
Other (specify) [5]										<u> </u>	
Exam Type, Means of Access											_
Transesophageal											
Transrectal											
Transvaginal											<u> </u>
Transurethral											_
Intraoperative(specify) [6]								<u> </u>			<u> </u>
Intraoperative Neurological											
Intravascular											L
Laparoscopic N = new indication: P = new							1			<u> </u>	

Intravascular								
Laparoscopic							LI	
N = new indication; P = prev	iously cleared by F	DA; E = adc	led under App	endix E		_		
Notes: [1] Abdominal inclu	ides GYN and Urol	ogical	•	\sim	1/2	< P.	10	
(2) Small organ incl	udes breast, testes,	thyroid.		_//	Juny-		<u> </u>	
[3] Cardiac is Adult	and Pediatric.		•		Division of R	on Sign-Off	l) Dovines	
[4] For detection of	fluid and pleural m	otion/sliding	;	Office of In V	itro Diagnost	ic Device E	valuation a	and Safety
[5] Other use includ					K 11:	260	A	
[6] Intraoperative in	cludes abdominal,	thoracic and p	peripheral;	51CK		107	\mathcal{U}_{-}	
[*] Combined mode [*] Coded Pulse is for			/D, B/Power/I	PWD.				

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with 16L-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

l.					M	ode of Op				т	
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging		
Ophthalmic											
Fetal / Obstetrics								ļ			
Abdominal									<u> </u>		_
Pediatric	P	P	P		P		P	P	P	P	
Small Organ [2]	P	P	P		P		P	P	P	P	_
Neonatal Cephalic								ļ			_
Adult Cephalic					<u> </u>						
Cardiac							ļ		<u> </u>		_
Peripheral Vascular	P	P	P		P	<u> </u>	P	P	P	P	<u> </u>
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P	L
Thoracic/Pleural(specify)[4]					<u> </u>	<u> </u>				ļ	_
Other (specify) [5]						<u> </u>	<u> </u>				_
Exam Type, Means of Access											_
Transesophageal		L				<u> </u>					<u> </u>
Transrectal							<u> </u>			 	_
Transvaginal							<u> </u>	<u> </u>	<u> </u>	ļ	<u> </u>
Transurethral		<u> </u>			ļ		ļ	ļ			₩
Intraoperative(specify) [6]				ļ			 			1	_
Intraoperative Neurological									<u> </u>		
Intravascular					<u> </u>			_		ļ	╄
Laparoscopic						- Appendi					1_

Neurological									<u> </u>		
Intravascular											
Laparoscopic				,,-,-					<u></u>		
N = new indication; P = pret Notes: [1] Abdominal inch [2] Small organ inc. [3] Cardiac is Adult [4] For detection of [5] Other use includ [6] Intraoperative in [*] Combined mode [*] Coded Pulse is f	ides G ludes t and P fluid i les Uri icludes s are l	YN and preast, to rediatrice and pleu plogy/P s abdom B/M, Bo	Urologiestes, thy i. iral moti rostate ninal, the (PWD, B	ical /roid. on/sliding oracic and //Color/P\	; peripheral	Offic	0 co of in Vi	Mac. (Dyfision of Retro Diagnosi	SAA on Sign-Off ediological tic Device E	Devices	and Safet
	arren	ce of C			CONTIN O Vitro Di				NEEDEL	D _	

GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with i12L-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					M	ode of Op	cration				
Clinical Application Anatomy/Region of Interest	В	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic										_	
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ [2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic							ļ				
Adult Cephalic											
Cardiac ^[3]	P	P	P		P		P	P	P	<u> </u>	
Peripheral Vascular	P	P	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		Р	Р	P	<u> </u>	
Musculo-skeletal Superficial	P	P	P		P		P	P	P	ļ	
Thoracic/Pleural(specify)[4]						<u> </u>				1	
Other ^[5]				<u> </u>			<u> </u>				ļ
Exam Type, Means of Access											
Transesophageal							<u> </u>			↓	<u> </u>
Transrectal				<u> </u>						 _ _ 	
Transvaginal				1			<u> </u>			<u> </u>	<u> </u>
Transurethral			<u> </u>			<u> </u>		ļ		-	
Intraoperative (specify) [6]	P	P	P		P		P	P	P	<u> </u>	
Intraoperative Neurological										_	
Intravascular										↓	
Laparoscopic N = new indication; P = pre-			<u></u>	1				mar		<u> </u>	

i = nev	w indication; $P = previously cleared by FDA; E = added under App$	sendix E Mary 3 (Coly)
lotes:	[1] Abdominal includes GYN and Urological	(Division Sign-Ott)
	[2] Small organ includes breast, testes, thyroid.	Division of Redictoglad Devices
	[3] Cardiac is Adult and Pediatric.	Office of In Vitro Diagnostic Device Evaluation and Safe
	6-3	510K B 1 3690
	[4] For detection of fluid and pleural motion/sliding;	510K 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
	[5] Other use includes Urology/Prostate	

[6] Intraoperative includes abdominal, thoracic and peripheral;[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[*] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with i/t739-RS Transducers

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					M	ode of O	peration				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler		Color M Doppler		Combined Modes	Harmonic Imaging		Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P		P		P	P	P		
Pediatric .	P	P	P		P		Р	P	P	<u> </u>	
Small Organ [2]	P	P	P_		P		P	P	P	L	
Neonatal Cephalic			<u></u>							1	
Adult Cephalic											
Cardiac ^[3]	P	P	P		P		P	P	P	<u> </u>	
Peripheral Vascular	P	P	P		P		P	P	P	<u> </u>	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural(specify)[4]								<u> </u>		↓	
Other ^[4]							<u> </u>			ļ	
Exam Type, Means of Access											
Transesophageal								<u> </u>			ļ
Transrectal								<u> </u>			ļ
Transvaginal						1	<u> </u>			↓	
Transurethral					1					-	
Intraoperative (specify) [6]	P	P	P		P	ļ	P	P	P		-
Intraoperative Neurological											
Intravascular											
Laparoscopic											<u> </u>

Laparo	scopic											
	v indication; P = prev					ed under	Appendi	XE C)	_	_	
lotes:	[1] Abdominal inclu	ides G	YN and	l Urologic	al				21.	5/27	+0	•
	[2] Small organ inci	udes t	reast, t	estes, thyr	oid.		-		Divisio	n Sign-Off		
	[3] Cardiac is Adult	and P	ediatric	P.				D	ivision of Re	diological C	in anna	
	[4] For detection of	fluid a	ınd pleı	ıral motio	n/sliding;		Offi	ce of In Vit	ro Diagnostic	Device Ev	aluation	and Safety
	[5] Other use include	les Un	ology/P	rostate					411:	260	N	·
	[6] Intraoperative in	cludes	abdon	inal, ther	acic and p	eripheral	;	510K		707	0	
	[*] Combined mode	s are l	B/M, B/	PWD, B/	Color/PW	D, B/Pov	ver/PWD).				
	[*] Coded Pulse is f	or digi	tally en	coded har	monics.							

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with 3S-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					M	ode of O					
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler		Color M Doppler		Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	Р	P	P	P	P	P	P	P	P	P	
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ [2]									ļ	-	
Neonatal Cephalic										<u> </u>	
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular	N	N	N	N	N	N	N	N	N	N	
Musculo-skeletal Conventional										ļ	
Musculo-skeletal Superficial											
Thoracic/Pleural(specify)[4]	P	P	P	P	P	P	P	P	P	P	
Other ^[5]	P	P	P	P	P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal					<u></u>						
Transrectal						<u> </u>	<u> </u>			—	Ļ
Transvaginal					1		<u></u>	<u> </u>		1	<u> </u>
Transurethral								<u> </u>		 	<u> </u>
Intraoperative (specify) [6]				<u> </u>	1	 		<u> </u>	1	-	↓
Intraoperative Neurological											
Intravascular									1	ļ	
Laparoscopic							ļ			<u> </u>	

	1000 PTO			***		Commence of the last		
N = nev	v indication; P = prev	iously cleared	by FDA;	E = adde	d under Appe	ndix E	200	0
Notes:	[1] Abdominal inclu	des GYN and	l Urological	,		/	lan.	State
	[2] Small organ incl	udes breast, t	estes, thyroi	d.			(Diylar	on Sign-Off)
	[3] Cardiac is Adult	and Pediatric		•		Office of in		
	[4] For detection of	fluid and plei	ral motion/	sliding;			Vido Diagnosti	c Device Evaluation and Safety
	[5] Other use includ	es Urology/P	rostate			510K	h 113	690
	[6] Intraoperative in	cludes abdon	ninal, thorac	ic and pe	eripheral;			

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[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[*] Coded Pulse is for digitally encoded harmonics.

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with 6S-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

			·			ode of O					
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppled	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P_	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ [2]			ļ								
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional	,										
Musculo-skeletal Superficial								_			
Thoracic/Pleural(specify) [4]											
Other ^[5]	P	P	P	P	P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal								<u> </u>			
Transrectal							<u> </u>				
Transvaginal										-	
Transurethral										<u> </u>	
Intraoperative (specify)[6]								<u> </u>	<u> </u>		
Intraoperative Neurological											
Intravascular		L			1						<u> </u>
Laparoscopic								<u> </u>			

Lapar	Scopic		1								
N = nev	v indication; P = prev	iously cleare	d by FDA;	E = adde	ed under	Appendix	(E)	h	-0	40	
Notes:	[1] Abdominal inch	ides GYN an	d Urologic	al		-		Const.	on Sign-Off	7 <i>1</i> -1	-
	[2] Small organ incl	ludes breast,	testes, thyr	oid.			D	ivision of R	diological I	Davicas	
	[3] Cardiac is Adult	and Pediatri	c.			Offic	of in Vit	ro Diagnost	ic Dovice E	valuation (and Sa
	[4] For detection of	fluid and ple	ural motio	n/sliding;			K	1112	600		
	[5] Other use includ	les I Imlagy/I	mstate				510KL	<u> </u>	OAR		

[6] Intraoperative includes abdominal, thoracic and peripheral;

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[*] Coded Pulse is for digitally encoded harmonics.

[5] Other use includes Urology/Prostate

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with P2D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation												
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler		Harmonic Imaging	Coded Pulse	Other		
Ophthalmic													
Fetal / Obstetrics													
Abdominal ^[1]													
Pediatric													
Small Organ [2]													
Neonatal Cephalic													
Adult Cephalic		<u>L</u> _											
Cardiac ^[3]				P									
Peripheral Vascular				P									
Musculo-skeletai Conventional													
Musculo-skeletal Superficial													
Thoracic/Pleural (specify) [4]													
Other ^[5]													
Exam Type, Means of Access													
Transesophageal													
Transrectal					L								
Transvaginal										1			
Transurethral		L	ļ				<u> </u>			 _ 			
Intraoperative (specify) [6]				1		<u> </u>				ļ			
Intraoperative Neurological							<u> </u>						
Intravascular	_	ļ					1				<u> </u>		
Laparoscopic N = new indication; P = pre										<u> </u>			

Lapar	oscopic											
	w indication; P = pre-	ides G indes I and P fluid : les Un	YN and preast, to rediatrice and plead plogy/P B/M, Ba	d Urologic estes, thyr c. ural motion rostate /PWD, B/6	al oid. n/sliding Color/PW	;	Office	ce of In Vi	Maria (Division of Ra itro Diagnosti (113)	h Sign-Off diological (Device Ev		end Safet
	(PLEASE DO NOT						IUE ON A			NEEDED)	

GE Compact Ultrasound LOGIO i, LOGIO e, Vivid e with 6Tc-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					M	lode of Or					
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler		Combined Modes	Harmonic Imaging		Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]											
Pediatric											
Smail Organ [2]											<u> </u>
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	!
Peripheral Vascular					ļ		ļ				<u> </u>
Musculo-skeletal Conventional											_
Musculo-skeletal Superficial											
Thoracic/Pleural (specify)[4]										<u> </u>	
Other ^[5]						<u> </u>					<u> </u>
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P	P	-
Transrectal										<u> </u>	
Transvaginal										<u> </u>	1
Transurethral						<u> </u>					
Intraoperative (specify) ^[6]											!
Intraoperative Neurological											
Intravascular											_
Laparoscopic				F = add					<u></u>	<u> </u>	

ew indication; $P = previously$ cleared by PDA; $E = added$ under A	ppenaix E
: [1] Abdominal includes GYN and Urological	m. alu
[2] Small organ includes breast, testes, thyroid.	- land lastel
[3] Cardiac is Adult and Pediatric.	Office of In Vitro Classics of In Vitro Classics
[4] For detection of fluid and pleural motion/sliding;	Office of In Vitro Diagnostic Dovice Evaluation and Safe
[5] Odiet me miermees er ereByr resume	VIII COA
	510K_D11.369()
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power	er/PWD.
[*] Coded Pulse is for digitally encoded harmonics.	
	[1] Abdominal includes GYN and Urological [2] Small organ includes breast, testes, thyroid. [3] Cardiac is Adult and Pediatric. [4] For detection of fluid and pleural motion/sliding;

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

GE Compact Ultrasound LOGIQ i, LOGIQ e, Vivid e with L8-18i-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation													
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler		Color M Doppler		Combined Modes*	Harmonic Imaging	Coded Pulse	Other			
Ophthalmic														
Fetal / Obstetrics														
Abdominai ^[1]	N	N	N		N		N	N	N	N				
Pediatric	N	N	N		N		N	N	N	N				
Small Organ [2]	N	N	N		N		N	N	N	N				
Neonatal Cephalic														
Adult Cephalic														
Cardiac ^[3]						-					-			
Peripheral Vascular	N	N	N		N		N	N	N	N				
Musculo-skeletal Conventional	Z	Z	N		N		N	N	N	N				
Musculo-skeletal Superficial	Z	N	N		N		N	N	N	N				
Thoracic/Pleural(specify) ^[4]	N	N	N		N		N	N	N	N				
Other ^[5]														
Exam Type, Means of Access														
Transesophageal														
Transrectal														
Transvaginal														
Transurethral														
Intraoperative (specify) [6]														
Intraoperative Neurological														
Intravascular														
Laparoscopic										1				

Laparo	scopic											
N = nev	v indication; P = prev	iously	cleared	by FDA	\; E = ade	led under	Appendi	κE				
	[1] Abdominal inch [2] Small organ incl [3] Cardiac is Adult [4] For detection of [5] Other use includ [6] Intraoperative in [*] Combined mode [*] Coded Pulse is for	udes to and P fluid a es Ura cludes s are l	YN and oreast, to ediatric and pleu ology/Po abdom B/M, B/	Urologicstes, thy aral motion rostate ainal, tho PWD, B	ical roid. on/sliding racic and /Color/PV	; peripheral	Office 51	Divis of in Vitro ((Dyslansion Redio Diagnostic O	logical Dev	tel ices lation an	nd Sede
	(PLEASE DO NOT	WRII	E BEL	OWTH	S LINE -	CONTIN	UE ON A	NOTHER	R PAGE IF	NEEDED	<u>. </u>	

Prescription Use (Per 21 CFR 801.109)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)